PRESCRIPTION DRUG ABUSE: WHAT IS BEING DONE TO ADDRESS THIS DRUG EPIDEMIC?

Statement of: LAXMAIAH MANCHIKANTI, MD

Chief Executive Officer

American Society of Interventional Pain Physicians

2831 Lone Oak Road • Paducah, KY 42003
PHONE: 270-554-8373 EXT. 107 • FAX: 270-554-8987 • E-MAIL: DRM@APEX.NET

BEFORE:

SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY, AND HUMAN RESOURCES

The American Society of Interventional Pain Physicians is an organization representing interventional pain physicians and other health care professionals involved in interventional pain management. Our membership is 3,700 at the present time. It is estimated that there are 6,500 interventional pain physicians across the country practicing interventional pain management. Interventional pain management, as per NUCC, is defined as — "the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment." As interventional pain physicians, our members are involved extensively in prescribing controlled substances, even though not to the same extent as non-interventional pain physicians whose mainstay of treatment of chronic pain is controlled substances.

The misuse and abuse of controlled substances, especially those containing opiates, among the general public and in patients suffering with chronic pain is a problem attracting nationwide attention. This fact is reinforced by multiple committees with jurisdiction over the epidemic, numerous hearings conducted by various committees, and the focus of numerous agencies. As an interventional pain physician, I am always humbled to note the course of two pioneers with diametrically opposing views that conveyed the same message: "We physicians know little and sometimes can do less."

Voltaire said.

"Doctors are men who give drugs of which they know little, into bodies of which they know less, for diseases of which they know nothing at all."

Albert Schweitzer said,

"Pain is a more terrible lord of mankind, than even death itself"

Both views remain true even today, despite numerous scientific advances in medicine. America and the world have entered into an era where we have to look at a different problem – prescription drug abuse, the byproduct of compassion coupled with a lack of understanding of the complex puzzle of pain and its management. Our nation is facing an epidemic of prescription drug abuse and addiction. Abuse of prescription drugs has been steadily, but sharply, rising.

1. Chronic pain is an epidemic in the United States

- Chronic pain is pain that persists beyond the usual course of an acute disease or a reasonable time for an injury to heal that is associated with chronic pathological processes that cause continuous pain or pain at intervals for months or years (1, 2); or
 - Persistent pain that is not amenable to routine pain control methods; or
 - Pain where healing may never occur.
- ♦ The prevalence of chronic pain in the adult population ranges from 2% to 40%, with a median point prevalence of 15% (3-5).
 - Persistent pain was reported with an overall prevalence of 20% of primary care patients, with approximately 48% reporting back pain (6).
- ♦ Chronic pain spares no one. It involves children and elderly alike (1-12).
 - Even though, historically, back pain research has primarily focused on younger, working adults, there is evidence that back pain is one of the most frequent complaints in older persons (11-14), and is an independent correlate of functional limitations (15, 16), perceived difficulty in performing daily life activities (17), and a risk factor for future disability.

- Chronic pain with involvement of multiple regions is a common occurrence in over 60% of the patients (18).
- ◆ Duration of pain and its chronicity are topics of controversy, with conventional beliefs that most episodes of low back pain will be short-lived with 80% to 90% of attacks resolving in about 6 weeks irrespective of the administration or type of treatment, and with 5% to 10% of patients developing persistent back pain.
 - This concept has been questioned as the condition tends to relapse and most patients will experience recurrent episodes.
 - Modern evidence has shown that chronic persistent low back pain and neck pain, not only in adults but also in children, are seen in up to 60% of patients for 5 years or longer after the initial episode (3, 7).
- ♦ Chronic non-cancer pain is associated with significant economic, societal, and health impact (1, 2, 23-26).
 - The cost of uncontrolled chronic pain is enormous both to individuals and society as it leads to a decline in quality of life and disability (1, 2).
 - Estimated in patterns of direct healthcare expenditures among individuals with back pain in the United States reached \$90.7 billion for the year 1998 (23).
 - On average, individuals with back pain generate healthcare expenditures about 60% higher than individuals without back pain.
 - The healthcare for patients with chronic pain might exceed the combined cost of treating patients with coronary artery disease, cancer, and AIDS (27).
- In the last several years, health policy-makers, health professionals, regulators and the public have become increasingly interested in better pain therapy provisions.

2. Prescription drug abuse for non-medical purposes is becoming an epidemic

- Non-medical uses of psychotherapeutics as described in multiple surveys include non-medical use of any prescription type of drugs (not including OTC):
 - Pain relievers
 - Tranquilizers
 - Stimulants
 - Sedatives
- The 2004 Survey on Drug Use and Health (NSDUH) (28) showed startling statistics.
 - An estimated **19.1 million** Americans or 7.9 percent of the population aged 12 and older **used illicit drugs** in 2004.

- 2.4 million persons used pain relievers non-medically for the first time within the past 12 months.
- Almost half of all Americans have tried an illicit drug at least once in their lifetime.
- The rate of illicit drug use among youth was 10.6 percent.
- 2.1 million persons had used marijuana for the first time within the past 12 months.
- Approximately **one in six youths is approached** by someone selling drugs.
- While the true extent of prescription drug abuse and diversion is unknown, estimates from a national survey indicate that the principle drug of abuse for nearly 10% of U.S. patients in treatment is a prescription drug.
- The most commonly abused drugs include oxycodone (Percodan®, Percocet®, Roxicet®, Tylox®, OxyContin®), hydrocodone (Vicodin®, Vicoprofen®, Lorcet®, Lortab®), hydromorphone, morphine (Astramorph®, Duramorph®, MS Contin®, Roxanol®), codeine, clonazepam (Klonopin®), alprazolam (Xanax®), lorazepam (Ativan®), diazepam (Valium®) and carisoprodol (Soma®) (28-30).
- The survey of Diversion and Abuse of Controlled Prescription drugs in the United States by the Center on Addiction and Substance Abuse (CASA) (30) revealed startling statistics.

• Between 1992 and 2003:

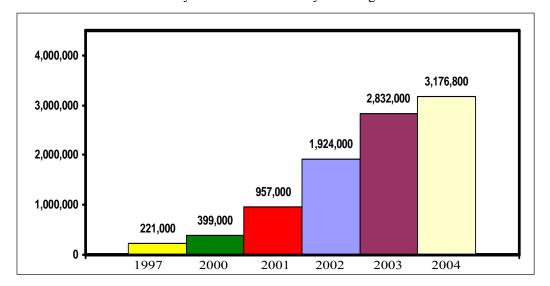
- The U.S. population increased 14%
- The number of people abusing prescription controlled substances increased by 94%
- 200% ↑ of Marijuana use
- 500% ↑ of Cocaine use
- 6,000% ↑ of Heroin use
- 212% ↑ in 12-17 years olds
- 542% ↑ new drug use among teens
- Most people (75%) are polysubstance abusers

♦ The 2004 NSDUH survey showed lifetime non-medical use of psychotherapeutics has increased to 20% of the population or 48 million adults in America.

		Current (millions)	Past Year (millions)	Lifetime (millions)
•	Pain relievers	4.4	11.3	31.8
•	OxyContin®	0.33	1.2	3.1
•	Tranquilizers	1.6	5.1	19.9
•	Stimulants	1.2	3.0	20.0
•	Methamphetamine	0.6	1.4	11.7
•	Sedatives	0.27	0.7	9.9
	Total	6.0	14.6	48.0
	Percentage	(2.5%)	(6.1%)	(20%)

- From 2003 to 2004, there were significant increases in lifetime prevalence use for specific pain relievers.
 - Hydrocodone products
 - ↑ from 31.3% to 33.9%
 - Oxycodone products (OxyContin® not included)
 - ↑ from 16.7% to 18.8%
 - OxyContin®
 - ↑ from 3.6% to 4.3%
- ♦ The Drug Abuse Warning Network (DAWN) (31) examined the involvement of opiates and deaths related to drug misuse.
 - Nearly 1.3 million emergency department (ED) visits in 2004 were associated with drug misuse/abuse.
 - Nonmedical use of pharmaceuticals was involved in nearly a half million of these ED visits.
 - Opioids > 158,000
 - Benzodiazepines > 144,000
 - Opiates/opioid analgesics (pain killers) and benzodiazepines were each present in more than 100,000 ED visits in 2004.
 - Muscle relaxants, particularly carisoprodol and cyclobenzaprine, were involved in an estimated 28,000 ED visits.
 - Two-thirds or more of ED visits associated with opiates/opioids, benzodiazepines, and muscle relaxants involved multiple drugs, and alcohol was one of the other drugs in about a quarter of such visits.
- Characteristics of recent initiatives for non-medical use of pain relievers is as follows (28):

- In 2004, among persons aged 12 or older, 2.4 million initiated non-medical use of prescription pain relievers within the past year
- There were 615,000 new non-medical users of OxyContin® in 2004
- Three-fourths (73.8 percent) of past year initiates of non-medical pain reliever use had used another illicit drug prior to using pain relievers non-medically
- Nearly all (99.1 percent) past-year initiates of non-medical OxyContin® use had used another illicit drug prior to using OxyContin® non-medically
- ♦ Non-medical use of OxyContin® has been skyrocketing.

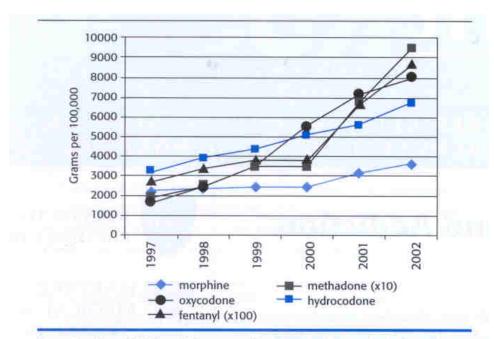


A recent survey of *USA Today* published on July 20, 2006 stated that 1 in 5 adults have a close relative who is or was addicted to drugs or alcohol.

3. Sharp increases in therapeutic use of controlled substances and misuse or abuse of controlled substances

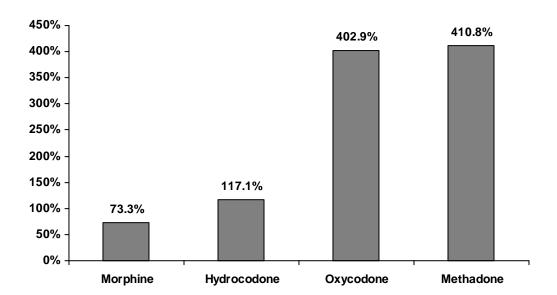
- Considerable controversy exists about the use of opioids for treatment of chronic pain of non-cancer origin.
 - Inadequate treatment of pain has been attributed to a lack of knowledge about pain management options, inadequate understanding of addiction, or to fears of investigation or sanction by federal, state, and local regulatory agencies (2, 29).
 - Many authors contend that drug therapy with opioid analgesics plays an important role in pain management and should be available when needed for all types of pain.
 - The DEA also took the position that clinicians should be knowledgeable about using opioids to treat pain and should not hesitate to prescribe them when opioids are the best clinical choice of treatment.
 - The alleged undertreatment of pain as a major health problem in the United States led to the development of initiatives to address the multiple alleged barriers responsible for the undertreatment of pain.
 - Patient advocacy groups and professional organizations have been formed with a

- focus on improving the management of pain.
- Numerous clinical guidelines also have been developed, even though none of them have been developed using evidence-based medicine.
- Extensive systematic review of the literature (2) showed that long-term use of opioids has not been well studied. Among the studies presented, it has been shown that opioids generally provide approximately 40% relief in 40% of the patients.
- Opioid use and subsequent use of other controlled substances for chronic pain has been increasing rapidly.
 - Over 90% of patients presenting to and in pain management centers are on opioids (32-35).
 - U.S. Office-based prescriptions have increased
 - All opioids
 - o 8% in 1980
 - o 16% in 2000
 - Schedule II
 - o 2% in 1980
 - o 9% in 2000
 - The increase in therapeutic opioid use in the U.S. from 1997 to 2002 has been substantial.



Data taken from: U.S. Drug Enforcement Administration. Automation of Reports and Consolidated Orders System (ARCOS); http://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

- Another frequent form of obtaining opioids included "street purchase" by 26% of the patients.
- In Methadone maintenance treatment (56), 83% of patients at admission had been using prescription opioids with or without heroin.
- Between 1992 and 2002, while the population of the United States increased by 13% and the number of prescriptions written for non-controlled drugs increased by 57%, the number of prescriptions filled for controlled drugs increased by 154%.
 - During this same period, there was a 90% increase (from 7.8 million to 14.8 million) in the number of people who admitted abusing controlled prescription drugs (30).
- Sales of opioids in grams increased significantly from 1997 to 2002 with an approximate 400% increase for oxycodone and methadone and over 110% increase for hydrocodone use. The following shows opioid sales in grams from 1997 to 2002.



- Drug abuse in chronic pain management is common.
 - Substance abuse in interventional pain management settings has been shown to be 9% to 24% (33, 34, 36-50).
 - With prevalence of chronic pain ranging from 15% to 30% in the United States (25 to 45 million persons), the prescription drug abuse or misuse is seen in 9% to 24% (approximately 3 million to 9 million persons).
 - The illicit drug use among patients in chronic pain receiving controlled substances has been shown to be 14% to 32%.

- Based on their type of insurance, the prevalence of illicit drug use among individuals with chronic pain was shown to be highest in patients on Medicaid (51).
- Prevalence of mental illness is almost double in patients with drug abuse (28).
- The interest in managing chronic pain has lead to increased prescription of controlled substances, fueled by:
 - Pharmaceutical companies providing marketing and gifts.
 - Numerous organizations providing guidelines and standards.
 - Patient advocacy groups demanding opioids for benign pain.
 - Enactment of the Patient's Bill of Rights in many states.
 - Unproven JCAHO regulations mandating monitoring and appropriate treatment of pain, which is misunderstood by the media and the public.
 - Patient's right to pain relief.
 - Easy availability on internet.
 - Unscrupulous providers.
 - Street value of prescription drugs.
 - Legitimacy provided by prescription drugs.
 - Safety and purity of prescription drugs.

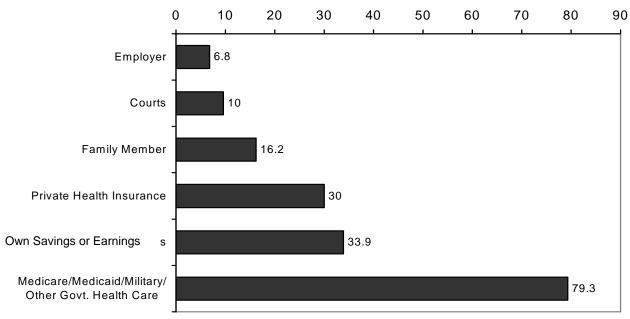
4. Drug diversion is an epidemic in the United States

- Drugs can be diverted from their lawful purpose to illicit ease at any point in the pharmaceutical manufacturing and distribution process. The diversion of prescription drugs among adults is typically described to occur through one of the following:
 - Doctor shopping
 - Illegal internet pharmacies
 - Prescription forgery
 - Illicit prescriptions by physicians
 - Youths typically acquire drugs by stealing from their relatives or buying from classmates who sell their legitimate prescriptions.
- ◆ Doctor shopping is one of the most common methods of obtaining prescription drugs for legal and illegal use (2, 31-50).
 - The majority of physicians perceive doctor shopping as the major mechanism of diversion (30).
 - Doctor shopping typically involves an individual going to several different doctors complaining of a wide array of symptoms in order to get prescriptions. This type of diversion can also involve individuals who use people with legitimate medical needs, like cancer patients, to go to various physicians in several cities to get prescription medications.
 - Patients practicing doctor shopping may target physicians who readily dispense prescriptions without physical examination or screening.
 - Some patients with a legitimate medical condition may get prescriptions from multiple physicians in various states or in the same state (52). It has been reported that individuals may collect thousands of pills during a one-year period and sell them on the street.

- Recently, some elderly have been supplementing their Social Security checks by selling part of their prescriptions.
- One specific area in which diversion has increased dramatically is through the use of the internet.
 - CASA (30) has reported the number of internet pharmacies in operation at any one time has reached as high as 1,400.
 - In 2001, prescription drug abuse and misuse was estimated to impose approximately \$100 billion annually in healthcare costs.
 - ComScore networks reported that 17.4 million people visited an online pharmacy in the fourth quarter of 2004, an increase of 14% from the previous quarter (54).
 - Sixty-three percent of these sites did not require a prescription to obtain controlled substances.
- Prescription forgery can occur at any point from manufacturer to the patient. Thefts are on the rise, largely due to drastic increases in prescription drug abuse and high street prices (52).
 - Prescription forgery is also fairly common either by altering the prescription or stealing blank prescription pads in order to write fake prescriptions or creating prescriptions by a computer program.
 - The vast majority of prescription forgery is from non-health care professionals.
 - Illicit prescriptions written by physicians, is rare, but a real phenomenon.
 - Headlines are made describing criminal cases involving physicians who become involved in diverting prescription drugs for huge profits.
 - However, malprescribing, either due to lack of knowledge or due to prescribing inappropriately through "pill mills" is more common.

 Adverse actions taken by the DEA against physician prescribers has, in fact, decreased from 0.9% in 1999 to 0.05% in 2003, even though actions by medical licensure boards have been increasing slightly.
- The diversion and abuse of prescription drugs are associated with incalculable costs to society in terms of addiction, overdose, death, and related criminal activities. The DEA has stated that the diversion and abuse of legitimately produced controlled pharmaceuticals constitute a multi-billion dollar illicit market nationwide (53). As of February 2002, OxyContin® has been involved in 464 deaths from prescription drug abuse, as reported by DEA on the basis of medical examiners autopsy findings for 2000 and 2001 from 32 states.
- A substantial amount of drug diversion or drug abuse may be coming from Methadone clinics.
 - Methadone clinics do not just treat heroin addiction.
 - Patients are in the clinic as long as they can afford to stay.
 - High doses of methadone are given, creating addiction.
- Patients may be receiving Schedule II, III, and IV prescriptions from multiple practitioners who are unaware of the potential for drug interactions or of the potential for abuse, and diversion of certain medications.

- ◆ Drug spending is skyrocketing. Significant amounts of Medicaid funds are spent on abused drugs. Drug spending in some states has increased by 65% in 2003.
- Source of payment for specialty treatment or drug abuse and addiction treatment is highest for federal funds:



Percent Source of Payment for Treatment

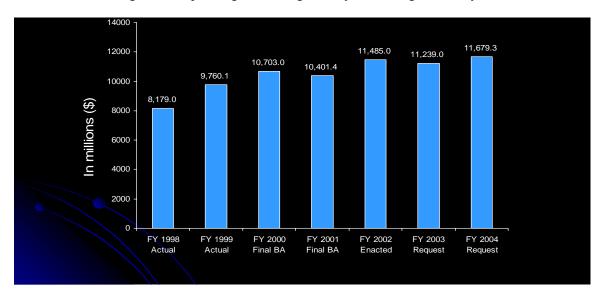
(Note that the estimates of treatment by source of payment include persons reporting more than one source.)

Source: 2002 National Survey on Drug Use and Health (NSDUH). Results from the 2002 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services

Costs to society of drug abuse has been skyrocketing. The following shows costs from 1992 to 2000 in millions of dollars.

Healthcare	Productivity		
costs	losses	Other	Total
10,820	69,421	21,912	102,153
11,279	82,685	24,440	118,404
11,428	92,423	27,444	131,295
12,862	98,467	32,083	143,412
14,899	110,491	35,274	160,664
	10,820 11,279 11,428 12,862	costs losses 10,820 69,421 11,279 82,685 11,428 92,423 12,862 98,467	costs losses Other 10,820 69,421 21,912 11,279 82,685 24,440 11,428 92,423 27,444 12,862 98,467 32,083

• Federal drug control spending has been gradually increasing over the years.



5. Problems facing physicians

- ♦ Role of physicians in controlling drug abuse. A CASA survey (30) of 979 physicians regarding the diversion and abuse of controlled prescription drugs showed the following:
 - Physicians perceive the three main mechanisms of diversion to be:
 - Doctor shopping (when patients obtain controlled drugs from multiple doctors) (96.4%)
 - Patient deception or manipulation of doctors (87.8%)
 - Forged or altered prescriptions (69.4%).
 - 59.1% believe that patients account for the bulk of the diversion problem.
 - 47.1% said that patients often try to pressure them into prescribing a controlled drug.
 - Only 19.1% of surveyed physicians received any medical school training in identifying prescription drug diversion.
 - Only 39.6% received any training in medical school in identifying prescription drug abuse and addiction.
 - 43.3% of physicians do not ask about prescription drug abuse when taking a patient's health history.
 - 33% do not regularly call or obtain records from the patient's previous (or other treating) physician before prescribing controlled drugs on a long-term basis. HIPPA regulations have made this step much more difficult.
 - 74.1% have refrained from prescribing controlled drugs during the past 12 months because of concern that a patient might become addicted to them.
- Every day physicians have to consider:

- Litigation for failure to treat pain
- Litigation for undertreatment
- Criminal charges for abuse, addiction, or death
- Numerous federal regulations
- State Board of Medical Examiners
- Drug Enforcement Agency
- State Bureau of Narcotics
- State Board of Pharmacy

♦ Options for Physicians

- Referral to Pain Medicine Clinics
 - Clinics with mainstay treatment of opioids
 - Very limited resource
 - Rare option for Interventional Pain Specialists
- Refuse to Prescribe Controlled Substances
 - Not an option for many practices
 - Inadequate treatment of pain lawsuits
 - Litigation for addiction
 - Criminal charges of murder
- Surrender Schedule II DEA License
 - Lose many patients
 - Lose hospital privileges
 - Lose all insurance patients
 - Not an option for interventionalists

6. Problems facing pharmacists

• The role of pharmacists:

A CASA survey of 1,303 pharmacists regarding diversion and abuse of controlled prescription drugs showed the following:

- When a patient presents a prescription for a controlled drug:
- 78.4% of pharmacists become "somewhat or very" concerned about diversion or abuse when a patient asks for a controlled drug by its brand name;
- 26.5% "somewhat or very often" think it is for purposes of diversion or abuse.
 - 51.8% believe that patients account for the bulk of the diversion problem.
 - Only about half of the pharmacists surveyed received any training in identifying prescription drug diversion (48.1%) or abuse or addiction (49.6%) since pharmacy school.
 - 61% do not regularly ask if the patient is taking any other controlled drugs when dispensing a controlled medication; 25.8% rarely or never do so.
 - 28.9% have experienced a theft or robbery of controlled drugs at their pharmacy within the last five years; 20.9% do not stock certain controlled drugs in order to prevent diversion.

- 28.4% do not regularly validate the prescribing physician's DEA number when dispensing controlled drugs; one in 10 (10.5%) rarely or never do so.
- 83.1% have refused to dispense a controlled drug in the past year because of suspicions of diversion or abuse.
- Pharmacists may be involved in prescription drug diversion, first by selling the controlled substances and then, using their database of physicians and patients to write and forge prescriptions to cover their illegal sale.

7. Problems facing legitimate patients

- ◆ Problem list:
 - Undertreatment of pain.
 - All patients are under suspicion.
 - The interest in receiving opioids for chronic pain, fueled by advertising by pharmaceutical companies.
 - Unproven, misunderstood JCAHO regulations mandating monitoring and appropriate treatment of pain.
 - Media coverage of undertreatment of pain.
 - Numerous organizations providing advocacy guidelines and standards.
 - Patient advocacy groups advising them to demand more opioids.
 - Access to internet and daily bombardment of easy availability of drugs.
 - Patient beliefs that they have the right to total pain relief.

A study evaluating severe dependence on oral opioids illustrated that the majority of patients with severe dependence (39%) obtained opioids by going to different physicians (50).

8. What is being done to address prescription drug abuse epidemic?

Drug Enforcement Agency

- On October 27, 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act. According to the DEA, Title 2 of this Act, The Controlled Substances Act, is a "consolidation of numerous laws regulating the manufacturing and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids and chemicals used in the illicit production of controlled substances" and is "the legal foundation of the governments fight against drugs and other substances" (57).
 - The Act also regulates all legal and illegal substances that are recognized as having potential for abuse or addiction (57).
 - The DEA's diversion control program oversees and regulates the legal manufacture and distribution of controlled pharmaceuticals (57).
 - DEA believes that controlled pharmaceuticals can be diverted intentionally or unintentionally by doctors, pharmacists, dentists, nurses, veterinarians, and individual users.
 - Diversion cases may involve physicians who sell prescriptions to drug dealers or abusers, pharmacists who falsify records to obtain and then

sell pharmaceuticals, employees who steal from physician or pharmacy inventories, individuals who forge prescriptions, individuals who commit armed robbery of pharmacies and drug distributors, "doctor shoppers" who routinely visit multiple doctors complaining of the same ailment to obtain multiple prescriptions for controlled substances, and individuals who establish internet pharmacies that sell controlled pharmaceuticals without requiring prescriptions.

- In 2005, Congress emphasized its concern regarding the diversion of controlled pharmaceuticals. The house report on the Justice Department's fiscal year (FY) 2005 appropriations stated, . . . "DEA has demonstrated a lack of effort to address this problem".
- The house report on the Justice Department's fiscal year 2006 appropriations repeated the concerns from the previous year. The final appropriation for FY 2006 included an additional \$8.8 million and 41 positions for the DEA to improve intelligence support and \$4.7 million and 23 positions for additional agents to assist diversion control.
- The DEA made diversion control one of its strategic goals.
- The DEA increased resources for diversion control. DEA added 75 diversion investigator positions in 2004, 75 positions in 2005 and 40 additional positions in 2006.
- The DEA undertook more criminal diversion investigations and established far more performance measures. The DEA's performance measures showed that from FY 2002 to FY 2005 the number of diversion drug organizations disrupted increased from 454 to 474 and the number of diversion drug organizations dismantled increased from 474 to 594. DEA developed then operational internet strategy.

Prescription controlled drug monitoring programs.

- ♦ The National All Schedules Prescription Electronic Reporting (NASPER) Act, which ASIPP initiated and worked through three sessions of Congress to pass, was signed into law on August 11, 2005.
 - It authorizes spending of \$60 million from fiscal year 2006 to 2010 to create federal grants at the U.S. Department of Health and Human Services to help establish or improve state-run prescription drug monitoring programs.
 - NASPER is moving extremely slow with no funding committed yet.
- ♦ DEA/Harold Rogers and state monitoring programs. While state programs have been effective, the following deficiencies have been noted.
 - From 1940 to 1999, states have been able to establish only 15 functioning programs. The number of states with prescription drug monitoring programs has grown only slightly over the past decade, from 10 in 1992 to 15 in 2002.
 - It appears that now there are approximately 32 programs in the process.
 - The White House estimates an increase in drug monitoring programs within the next 10 years.
 - Even though the programs have a common goal of reducing prescription drug diversion and abuse, the programs vary in objectives, design, and operation.

- The major purpose of the state programs is to help law enforcement identify and prevent prescription drug diversion.
- Educational objectives to provide information to physicians, pharmacies, and the public is a secondary objective.
- Very few states are proactive to the extent that physicians can access the information to reduce or prevent abuse and diversion.
- Program design also varies across states in terms of which drugs are covered, how prescription information is collected, and which agency is given responsibility for the program.
- Methods for analyzing the data to detect potential diversion activity also differ among states.
- Only 4 of 15 states monitor Schedule IV drugs and only 5 of 15 monitor Schedule III drugs which are the subject of major controlled substance abuse.
- Challenges exist in establishing and expanding state programs, due to lack of awareness of the extent to which prescription drug abuse and diversion in a significant public health and law enforcement problem.
- Extent of diversion in abuse is not always recognized by the states.
- National efforts have focused only on providing guidance and technical assistance.
- Incidents of drug diversion, however, are on the rise in neighboring states, indicating the problem is proliferating or shifting to states without monitoring programs.

♦ State Regulations

- The state's regulation of practice of medicine and pharmacy and role in monitoring illegal use and diversion of prescription drugs. State laws govern the prescribing and dispensing of prescription drugs by licensed healthcare professionals.
- Multiple state agencies have responded to reports of drug abuse. However, complete information is not available from the directors of state Medicaid fraud control units in Kentucky, Maryland, Pennsylvania, Virginia, and West Virginia. They stated that drug abuse and diversion of OxyContin® is a problem in these states.
- State Medical Licensure Boards have also responded to complaints about physicians who were suspected of abuse and diversion of controlled substances, but like the Medicaid Fraud Control Units, the Boards generally do not maintain data on the number of investigations that were involved.

- Although Medical Boards may be tough, they can't always catch the bad apples
- The Board reacts to complaints and can't statutorily look for problems on its own

9. Strategies to combat the epidemic

- Education: Education is required at all levels including public, physicians and pharmacists.
 - Surveys have shown that less than 40% of physicians have received any training in medical school in identifying prescription drug abuse and addiction or identification of drug diversion. Similarly, only 50% of pharmacists received any training in identifying prescription drug diversion, abuse or addiction.
 - Controlled substance education must be mandated in medical schools, residency training programs, pharmacy schools, and supported by continuing education each year variable from 20 hours in the first year and 10 hours in subsequent years. The training must be accredited and approved and may be monitored mainly by DEA or State Board of Medical Licensures.
 - The public must be educated on nonopioid techniques of chronic pain management. In addition, public should be educated about overall ineffectiveness of opioid use, prevalence of misuse and adverse effects, even if used properly. The education should stress the disastrous consequences of misuse and abuse.
 - A separate residency program is needed in interventional pain management.
- ♦ Enactment of NASPER in all states:
 - NASPER is the best solution for a mounting problem in a proactive fashion.
 - NASPER is cost-effective and the information is shared by neighboring states. This will avoid all the disadvantages of people moving from one state to another.

Table 1 shows the contiguous states for each of the 50 states.

- NASPER is a physician friendly program, thus doctor shopping can be prevented rather than be dealt with by DEA with criminal charges.
- DEA should work with provider community. At present, the relationship between DEA and provider community including pharmacists is at best lukewarm. This relationship has to be improved.
 - DEA should encourage NASPER program as it is a proactive, physician friendly, all schedules and shares information among the contiguous states
 - Medicaid coverage for controlled substances should be looked at and regulated.
- Benefits of NASPER are numerous as follows:
- Benefits for Patients:
 - Improved access
 - Stable patient physician relationship

Honest patients receive appropriate treatment

- Benefits for Physicians:
 - Decreased hassle factors
 - DEA, Medical Board, U.S. Attorneys, and Renegade Physicians

Proper treatment without hassles

- Benefits for Law Enforcement:
 - Improved identification
 - Rapid prosecution
- Improve relationships between DEA and providers
- Increased scrutiny of methadone clinics
- Increased comprehensive drug rehabilitation programs
 - Buprenorphine detoxification
- Elimination of internet pharmacies

 Table 1. Shows the contiguous states for each of the 50 states

State	Surrounding States	
Alabama	Florida, Georgia, Mississippi, Tennessee	
Alaska	None	
Arizona	California, Colorado, New Mexico, Nevada, Utah	
Arkansas	Louisiana, Missouri, Mississippi, Oklahoma, Tennessee, Texas	
California	Arizona, Nevada, Oregon	
Colorado	Arizona, Kansas, Nebraska, New Mexico, Oklahoma, Utah, Wyoming	
Connecticut	Massachusetts, New York, Rhode Island	
Delaware	Maryland, New Jersey, Pennsylvania	
Washington DC	Maryland, Virginia	
Florida	Alabama, Georgia	
Georgia	Alabama, Florida, North Carolina, South Carolina, Tennessee	
Hawaii	None	
Idaho	Montana, Nevada, Oregon, Utah, Washington, Wyoming	
Illinois	Iowa, Indiana, Kentucky, Missouri, Wisconsin	
Indiana	Illinois, Kentucky, Michigan, Ohio	
Iowa	Illinois, Minnesota, Missouri, Nebraska, South Dakota, Wisconsin	
Kansas	Colorado, Missouri, Nebraska, Oklahoma	
Kentucky	Illinois, Indiana, Missouri, Ohio, Tennessee, Virginia, West Virginia	
Louisiana	Arkansas, Mississippi, Texas	
Maine	New Hampshire	
Maryland	District Of Columbia, Delaware, Pennsylvania, Virginia, West Virginia	
Massachusetts	Connecticut, New Hampshire, New York, Rhode Island, Vermont	
Michigan	Indiana, Ohio, Wisconsin	
Minnesota	Iowa, North Dakota, South Dakota, Wisconsin	
Mississippi	Alabama, Arkansas, Louisiana, Tennessee	
Missouri	Arkansas, Iowa, Illinois, Kansas, Kentucky, Nebraska, Oklahoma, Tennessee	
Montana	Idaho, North Dakota, South Dakota, Wyoming	
Nebraska	Colorado, Iowa, Kansas, Missouri, South Dakota, Wyoming	
Nevada	Arizona, California, Idaho, Oregon, Utah	
New Hampshire	Massachusetts, Maine, Vermont	
New Jersey	Delaware, New York, Pennsylvania	
New Mexico	Arizona, Colorado, Oklahoma, Texas, Utah	
New York	Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont	
North Carolina	Georgia, South Carolina, Tennessee, Virginia	
North Dakota	Minnesota, Montana, South Dakota	
Ohio	Indiana, Kentucky, Michigan, Pennsylvania, West Virginia	
Oklahoma	Arkansas, Colorado, Kansas, Missouri, New Mexico, Texas	

Oregon	California, Idaho, Nevada, Washington
Pennsylvania	Delaware, Maryland, New Jersey, New York, Ohio, West Virginia
Rhode Island	Connecticut, Massachusetts
South Carolina	Georgia, North Carolina
South Dakota	Iowa, Minnesota, Montana, North Dakota, Nebraska, Wyoming
Tennessee	Alabama, Arkansas, Georgia, Kentucky, Missouri, Mississippi, North Carolina, Virginia
Texas	Arkansas, Louisiana, New Mexico, Oklahoma
Utah	Arizona, Colorado, Idaho, New Mexico, Nevada, Wyoming
Vermont	Massachusetts, New Hampshire, New York
Virginia	District Of Columbia, Kentucky, Maryland, North Carolina, Tennessee, West Virginia
Washington	Idaho, Oregon
West Virginia	Kentucky, Maryland, Ohio, Pennsylvania, Virginia
Wisconsin	Iowa, Illinois, Michigan, Minnesota
Wyoming	Colorado, Idaho, Montana, Nebraska, South Dakota, Utah

REFERENCES

- Boswell MV, Shah RV, Everett CR, Sehgal N, Mckenzie-Brown AM, Abdi S, Bowman RC, Deer TR, Datta S, Colson JD, Spillane WF, Smith HS, Lucas-Levin LF, Burton AW, Chopra P, Staats PS, Wasserman RA, Manchikanti L. Interventional techniques in the management of chronic spinal pain: Evidence-based practice guidelines. *Pain Physician* 2005; 8:1-47.
- 2. Trescot AM, Boswell MV, Atluri SL, Hansen HC, Deer TR, Abdi S, Jasper JF, Singh V, Jordan AE, Johnson BW, Cicala RS, Dunbar EE, Helm II S, Varley KG, Suchdev PK, Swicegood JR, Calodney AK, Ogoke BA, Minore WS, Manchikanti L. Opioid guidelines in the management of chronic non-cancer pain. *Pain Physician* 2006; 9:1-40.
- Manchikanti L, Staats PS, Singh V, Schultz DM, Vilims BD, Jasper JF, Kloth DS, Trescot AM, Hansen HC, Falasca TD, Racz GB, Deer T, Burton AW, Helm S, Lou L, Bakhit CE, Dunbar EE, Atluri SL, Calodney AK, Hassenbusch S, Feler CA. Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician* 2003; 6:3-80.
- 4. Verhaak PF, Kerssens JJ, Dekker J, Sorbi MJ, Bensing JM. Prevalence of chronic benign pain disorder among adults: A review of the literature. *Pain* 1998; 77:231-239.
- 5. Blyth FM, March LM, Brnabic AJ, Jorm LR, Williamson M, Cousins MJ. Chronic pain in Australia: A prevalence study. *Pain* 2001; 89:127-134.
- 6. Gureje O, Von Korff M, Simon GE, Gater R. Persistent pain and well-being: A World Health Organization study in primary care. *JAMA*1998; 280:147-151.
- 7. Elliott AM, Smith BH, Hannaford PC, Smith WC, Chambers WA. The course of chronic pain in the community: Results of a 4-year follow-up study. *Pain* 2002; 99:299-307.
- 8. Bressler HB, Keyes WJ, Rochon PA, Badley E. The prevalence of low back pain in the elderly. A systemic review of the literature. *Spine* 1999; 24:1813-1819.
- 9. Lawrence RC, Helmick CG, Arnett FC. Estimates of the prevalence of arthritis and selected musculoskeletal disorders in the United States. *Arthritis Rheum* 1998; 41:778-799.

- 10. Mallen C, Peat G, Thomas E, Croft P. Severely disabling chronic pain in young adults: prevalence from a population-based postal survey in North Staffordshire. *BMC Musculoskeletal Disords* 2005, 6:42.
- 11. Cecchi F, Debolini P, Lova RM, Macchi C, Bandinelli S, Bartali B, Lauretani F, Benvenuti E, Hicks G, Ferrucci L. Epidemiology of back pain in a representative cohort of Italian persons 65 years of age and older: the InCHIANTI study. *Spine* 2006; 31:1149-1155.
- 12. Lavsky-Shulhan M, Wallace RB, Kohout FJ, Lemke JH, Morris MC, Smith IM. Prevalence and functional correlates of low back pain in the elderly: the Iowa 65+ Rural Health Study. *J Am Geriatr Soc*. 1985; 33:23-28.
- 13. Koch H, Smith MC. Office-based ambulatory care for patients 75 years old and over. National Ambulatory Medical Care Survey, 1980 and 1981. Advanced Data from Vital and Health Statistics (NCHS), No. 110 [DHHS Publication No, PHS 85-1250]. Hyattsville, MD: Public Health Service, 1985; 110:1-4.
- 14. Goel V, Iron k, Williams JL. Indicators of health determinants and health status. In: Goel V, Williams JI, Anderson GM, et al, eds. *Patterns of Health Care in Ontario*: *The ICES Pactice Atlas*, 2nd ed. Ottawa: Canadian Medical Association, 1996:5–26.
- 15. Hartley BB, Warren JK, Rachon PA, et al. The prevalence of low back pain in the elderly: a systematic review of the literature. *Spine* 1999;24:1813–9.
- 16. Edmond SL, Felson DT. Function and back symptoms in older adults. *J Am Geriatr Soc* 2003;51:1702–1709.
- 17. Leveille SG, Guralnik JM, Hochberg M, et al. Low back pain and disability in older women: independent association with difficulty but not inability to perform daily living activities. *J***Gerontol 1999; 54:M487–493.
- 18. Yeung SS, Genaidy A, Deddens J, Alhemood A, Leung PC. Prevalence of musculoskeletal symptoms in single and multiple body regions and effects of perceived risk of injury among manual handling workers. *Spine* 2002; 27:2166-2172.

- 19. Enthoven P, Skargren E, Oberg B. Clinical course in patients seeking primary care for back or neck pain: A prospective 5-year follow-up of outcome and health care consumption with subgroup analysis. *Spine* 2004; 29:2458-2465.
- Hoving JL, de Vet HC, Twisk JW, Deville WL, van der Windt D, Koes BW, Bouter LM.
 Prognostic factors for neck pain in general practice. *Pain* 2004; 110:639-645.
- 21. Smith BH, Elliott AM, Hannaford PC, Chambers WA, Smith WC. Factors related to the onset and persistence of chronic back pain in the community: Results from a general population follow-up study. *Spine* 2004; 29:1032-1040.
- 22. Cote P, Cassidy JD, Carroll LJ, Kristman V. The annual incidence and course of neck pain in the general population: A population- based cohort study. *Pain* 2004; 112:267-273.
- 23. Luo X, Pietrobon R, Sun SX, Liu GG, Hey L. Estimates and patterns of direct health care expenditures among individuals with back pain in the United States. *Spine* 2004; 29:79-86.
- Leigh JP, Markowitz SB, Fahs M, Shin C, Landrigan PJ. Occupational injury and illness in the United States. Estimates of costs, morbidity, and mortality. *Arch Intern Med* 1997; 157:1557-1568.
- 25. Freedman VA, Martin LG, Schoeni RF. Recent trends in disability and functioning among older adults in the United States. *JAMA* 2002; 288:3137-3146.
- 26. Turner JA, Franklin G, Heagerty PJ, Wu R, Egan K, Fulton-Kehoe D, Gluck JV, Wickizer TM.
 The association between pain and disability. *Pain* 2004; 112:307-314.
- 27. Hough J. Estimating the health care utilization costs associated with people with disabilities: Data from the 1996 Medical Expenditure Panel Survey (MEPS). *Annual meeting of the Association for Health Services Research*, Los Angeles, California, 2000.
- 28. Substance Abuse and Mental Health Services Administration (2004). Overview of Findings from the 2003 National Survey on Drug Use and Health (Office of Applied Studies, NSDUH Series H-24, DHHS Publication No. SMA 04-3963). Rockville MD.
- 29. Manchikanti L, Whitfield E, Pallone F. Evolution of the National All Schedules Prescription

- Electronic Reporting Act (NASPER): A public law for balancing treatment of pain and drug abuse and diversion. *Pain Physician* 2005; 8:335-347.
- 30. Bollinger LC, Bush C, Califano JA, Chenault KI, Curtis JL, Dimon J, Dolan PR, Ganzi VF, Fisher M, Kelmenson LA, Keough DR, Kessler DA, Malloy EA, Pacheco MT, Plumeri II JJ, Redstone SE, Rosenwald Jr EJ, Schulhof MP, Sullivan LW, Sweeney JJ, Wiener MA. Under the counter. The diversion and abuse of controlled prescription drugs in the U.S. The National Center on Addition and Substance Abuse at Columbia University (CASA), July 2005.
- 31. US Department of Health and Human Services. Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA). Drug Abuse Warning Network. The DAWN Report. Opiate-related drug misuse deaths in six states: 2003. Issue 19, 2006.
- 32. Manchikanti L, Damron KS, McManus CD, Barnhill RC. Patterns of illicit drug use and opioid abuse in patients with chronic pain at initial evaluation: A prospective, observational study. *Pain Physician* 2004; 7: 431-437.
- 33. Chabal C, Erjavec MK, Jacobson L, Mariano A, Chaney E. Prescription opiate abuse in chronic pain patients: Clinical criteria, incidence, and predictors. *Clin J Pain* 1997; 13: 150-155.
- 34. Katz NP, Sherburne S, Beach M, Rose RJ, Vielguth J, Bradley J, Fanciullo GJ. Behavioral monitoring and urine toxicology testing in patients receiving long-term opioid therapy. *Anesth Analg* 2003; 97:1097-1102.
- 35. Gajraj N, Hervias-Sanz M. Opiate abuse or undertreatment? Clin J Pain 1998; 14:90-91.
- 36. Manchikanti L, Pampati V, Damron K, Fellows B, Barnhill RC, Beyer CD. Prevalence of opioid abuse in interventional pain medicine practice settings: A randomized clinical evaluation. *Pain Physician* 2001; 4: 358-365.
- 37. Manchikanti L, Pampati V, Damron K. Prevalence of prescription drug abuse and dependency in patients with chronic pain in western Kentucky. *J KY Med Assoc* 2003; 101:511-517.
- 38. Kell M. Monitoring compliance with Oxy-Contin prescriptions in 14,712 patients treated in 127 outpatient pain centers. *Pain Med* 2005; 6:186-187.

- 39. Vaglienti RM, Huber SJ, Noel KR, Johnstone RE. Misuse of prescribed controlled substances defined by urinalysis. *W V Med J* 2003; 99:67-70.
- 40. Passik SD, Kirsh KL, McDonald MV, Ahn S, Russak SM, Martin L, Rosenfeld B, Breitbart WS, Portenoy RK. A pilot survey of aberrant drug-taking attitudes and behaviors in samples of cancer and AIDS patients. *J Pain Symptom Manage* 2000; 19:274-286.
- 41. Atluri S, Sudarshan G. A screening tool to determine the risk of prescription opioid abuse among patients with chronic nonmalignant pain. *Pain Physician* 2002; 5: 447-448.
- 42. Lentner S. *Drug abuse*. Winer Zeitschrift für Suchforschung 1991; 14:65-68.
- 43. Hurwitz W. The challenge of prescription drug misuse: A review and commentary. *Pain Med* 2005; 6:152-161.
- 44. Manchikanti L, Manchukonda R, Damron KS, Brandon D, McManus CD, Cash KA. Does adherence monitoring reduce controlled substance abuse in chronic pain patients? *Pain Physician* 2006; 9:57-60.
- 45. Manchikanti L, Cash KA, Damron KS, Manchukonda R, Pampati V, McManus CD. Controlled substance abuse and illicit drug use in chronic pain patients: An evaluation of multiple variables.

 *Pain Physician 2006; 9:215-226.
- 46. Ives TJ, Chelminski PR, Hammett-Stabler CA, Malong RM, Perhac JS, Potisek NM, Shilliday BB, DeWalt DA, Pignone MP. Predictors of opioid misuse in patients with chronic pain: A prospective cohort study. *BMC Health Serv Res* 2006; 6:46.
- 47. Manchikanti L, Pampati V, Damron K, Beyer CD, Barnhill RC. Prevalence of illicit drug use in patients without controlled substance abuse in interventional pain management. *Pain Physician* 2003; 6:173-178.
- 48. Manchikanti L, Beyer C, Damron K, Pampati V. A comparative evaluation of illicit drug use in patients with or without controlled substance abuse in interventional pain management. *Pain Physician* 2003; 6:281-285.
- 49. Manchikanti L, Damron KS, Pampati V, McManus CD. Prevalence of illicit drug use among

- individuals with chronic pain in the commonwealth of Kentucky: An evaluation of patterns and trends. *J KY Med Assoc* 2005; 103:55-62.
- Manchikanti L, Manchukonda R, Pampati V, Damron KS, Brandon DE, Cash KA, McManus CD. Does random urine drug testing reduce illicit drug use in chronic pain patients receiving opioids? *Pain Physician* 2006; 9:123-129.
- 51. Manchikanti L, Manchukonda R, Pampati V, Damron KS. Evaluation of abuse of prescription and illicit drugs in chronic pain patients receiving short-acting (hydrocodone) or long-acting (methadone) opioids. *Pain Physician* 2005; 8:257-261.
- 52. Kraman P. Drug abuse in America prescription drug diversion. The Council of State Governments. April 2004. www.csg.org
- 53. Drug Enforcement Administration and the National Alliance for Model State Drug Laws, *A closer Look at State Prescription Monitoring Programs*(http://www.deadiversion.usdoj.gov/pubs/program/prescription-monitor/summary.htm
- 54. ComScore is a global market research provider and consultant for Internet Usage, audience measurement, and e-commerce tracking data. The study is at www.comscore.com/press/release.asp?press=571.
- 55. Busto UE, Sproule BA, Knight K, Romach MK, Sellers EM. Severe dependence on oral opioids.

 *Can J Clin Pharmacol 1998; 5: 23-28.
- 56. Brands B, Blake J, Sproule BA, Gourlay D, Busto UE. Prescription opioid abuse in patients presenting for methadone maintenance treatment. *Drug Alcohol Depend* 2004; 73:199-207.
- 57. US Department of Justice Office of the Inspector General Evaluation and Inspections Division.

 Follow Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals. July 2006.